IN THE UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH CAROLINA
GREENVILLE DIVISION

STATE OF SOUTH CAROLINA)	C.A. No.: _____
)	
)	
James Thomason and Kaye Thomason,)	
)	
Plaintiffs,)	
)	**COMPLAINT**
-versus-)	
)	
Sorin Group Deutschland GMBH and)	**(Jury Trial Requested)**
Sorin Group USA, Inc.,)	
)	
)	
Defendants.)	

The Plaintiffs, complaining of the acts of the Defendants above named, would respectfully show unto the Court as follows:

PARTIES TO THIS ACTION

1. The Plaintiffs, James Thomason and Kaye Thomason, husband and wife, are residents and citizens of Greenville County, State of South Carolina. On March 21, 2014, the Plaintiff, Mr. Thomason, underwent a Coronary Artery Bypass Grafting procedure at the Greenville Health System Hospital ("GHS") in Greenville, South Carolina, during which the Sorin 3T Heater-Cooler System was utilized, exposing him to Nontuberculosis Mycobacteria.

2. Upon information and belief, the Defendant Sorin Group Deutschland GMBH ("Sorin") is a foreign for-profit corporation, with headquarters in Munich, Germany. Sorin designed, manufactured and marketed the Sorin 3T Heater-Cooler System used in the Plaintiff's surgical procedure in Greenville, South Carolina. The Plaintiffs are under the information and belief that Sorin is the entity responsible for

manufacturing the Sorin 3T Heater-Cooler Systems and distributing them to Sorin Group USA for marketing and distribution within the U.S.[1]

3. Upon information and belief, the Defendant Sorin Group USA, Inc. ("Sorin USA") is a United States designer, manufacturer, marketer, and distributor of the Sorin 3T Heater-Cooler System, with its principal place of business in Arvada, Colorado. Plaintiffs are under the information and belief that Defendants Sorin and Sorin USA are subsidiaries of LivaNova PLC, a company that serves solely as the "holding company" of Defendants Sorin and Sorin USA. Sorin USA is responsible for the marketing and distribution of the Sorin 3T Heater-Cooler Systems within the U.S.[2]

JURISDICTION AND VENUE

4. This Court has Personal Jurisdiction over this action pursuant to FRCP 4 and pursuant to SC Code Ann. § 36-2-803. The Defendants are non-domiciliaries of the State of South Carolina and contract business within the State of South Carolina; the Defendants have committed tortious acts within the State of South Carolina, causing injury to persons, including the Plaintiffs, within the State of South Carolina, and said Defendants expect or should reasonably expect to have consequences in the State of South Carolina; the Defendants solicit business and engage in persistent courses of conduct and derive substantial revenue from goods used and services rendered in the State of South Carolina; the Defendants are in the business of researching, designing, developing, testing, manufacturing, distributing, licensing, labeling, and marketing, either directly or indirectly through third-party related entities, Sorin Group Stockert Heater-Cooler 3T thermal regulator devices in the State of South Carolina.

[1] This information was obtained by Plaintiffs' counsel through previously filed Complaints and Answers in similar actions, which involve the same Defendants and the same or similar causes of action (i.e., *Fowler v. Sorin Group USA, Inc., et al.* C.A. # 6:16-cv-02307-BHH)
[2] Id.

5. This Court has Subject Matter Jurisdiction over this action pursuant to 28 U.S.C. § 1332 because complete diversity exists between the parties and the amount in controversy exceeds $75,000.00.

6. Venue is proper in the District of South Carolina pursuant to 28 U.S.C. § 1391(a)(2) because a substantial part of the events or omissions giving rise to the causes of action occurred in South Carolina and 28 U.S.C. § 1391(c) because Defendants are subject to Personal Jurisdiction in the District of South Carolina.

FACTUAL ALLEGATIONS

7. The Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation in this Complaint.

8. The Defendants manufacture, market, and sell/distribute thermal regulator devices to be used on patients in the operating room, including the Sorin 3T Heater-Cooler System ("Sorin 3T System").

9. Prior to March 21, 2014, the Defendants manufactured, introduced, and/or delivered for introduction into interstate commerce, the Sorin 3T System.

10. The Sorin 3T System is intended to provide temperature controlled water to heat exchanger devices (cardio-pulmonary bypass heat exchangers, cardioplegia heat exchangers, and thermal regulating blankets) to warm or cool a patient during cardio-pulmonary bypass procedures lasting six (6) hours or less. The Sorin 3T System is a Class II Medical Device that is subject to the Food and Drug Administration's ("FDA") Section 510K premarket notification process ("510K" or "510K process").[3]

[3] A 510K premarket notification is a premarket submission made to the FDA to establish that the device to be marketed is substantially equivalent to a legally marketed device that is not subject to premarket approval (PMA) 21 CFR 807.92(a)(3).

11. Before commercial distribution in the United States of the Sorin 3T System, Defendant Sorin submitted a 510K premarket notification of intent to market the Sorin 3T System with the Secretary of Health and Human Services for FDA approval. The FDA determined that the Sorin 3T System was substantially equivalent to legally marketed predicate devices that do not require approval of a premarket approval ("PMA") application. This determination was relayed to the Defendants via letter on June 6, 2006, 510K number K052601.[4] Essentially, the 510k process differs from the PMA process in how carefully the FDA examines the safeness of the medical device. The PMA process is required for Class III medical devices while Class I and Class II predicate medical devices can be approved through the less rigorous 510K process.

12. The FDA approval allows the Defendants to commercially distribute the Sorin 3T System in accordance with the conditions and regulations described in the approval letter. Any commercial distribution of the Sorin 3T System that does not comply with the conditions set forth in the letter are violations of the Federal Food, Drug, and Cosmetic Act ("the Act"). Generally, the manufacturer must comply with all of the Act's requirements, including but not limited to: "Registration and Listing (21CFR part 807); Labeling (21CFR part 801); Good Manufacturing Practice Requirements as set forth in the Quality Systems Regulation (21CFR part 820); and if applicable, the Electronic Product Radiation Control Provisions (Sections 531-542 of the Act); 21CFR 1000-1050."

13. On or about June 20, 2014, GHS publically announced that approximately 14 patients had tested positive for a rare non-tuberculosis mycobacterium infection,

[4] Please see the FDA Determination Letter of Approval attached hereto as "Exhibit A".

known as mycobacterium abscessus ("m. abscessus"). The majority of those patients were exposed to the bacterium during open heart surgeries. At that time, GHS indicated that there had been three (3) deaths resulting from the same infection. On or about June 26, 2014, GHS released a second statement indicating that there were 15 confirmed cases of patients with the infection. On July 21, 2014, GHS confirmed that the patient death toll had increased to four (4).

14. In the July 21, 2014 announcement, GHS stated that it sent out letters to "…approximately 180 patients on whom specific cardiopulmonary surgical equipment had been used" since those patients were at risk after potentially being exposed to the m. abscessus bacterium, including Plaintiffs.[5]

15. M. abscessus is a part of a group known as "rapidly growing mycobacteria" and is most commonly found in water, soil, and dust. If allowed within the operative field, it poses a significant health risk to surgical patients and patients that are immunodeficient.[6]

16. M. abscessus is a "slow growing bacterium" that can take anywhere from weeks to years before it manifests into a non-tuberculosis mycobacterium infection.

17. Tissue that has been infected with m. abscessus usually presents as "red, warm, tender to the touch, swollen, and/or painful" and infected areas can appear as "boils." Additional signs and symptoms of the infection include "fever, chills, muscles aches, and a general feeling of illness."[7]

18. Diagnosis of m. abscessus can be made from a laboratory analysis of a sample or biopsy of the infected area. In severe cases, the bacterium can be found in

[5] Please see "Exhibit B" attached hereto, which is a copy of the actual letter submitted to the patients by GHS.
[6] Centers for Disease control website: http://www.cdc.gov/HAI/organisms/mycobacterium.html
[7] Id.

the blood and isolated from a blood sample. Targeted cultures, screenings, and proper testing is usually not performed unless the physician has been made aware of this type of mycobacterium exposure. [8]

19. While death is certainly a risk of this type of infection, there are treatments available. Those include draining collections of pus or removing the infected tissue coupled with rigorous administration of a series of appropriate antibiotics for prolonged periods of time. The type and period of treatment can vary greatly from patient to patient.[9]

20. Investigations were undertaken by the South Carolina Department of Health and Environmental Control (SC DHEC) in an effort to determine the cause(s) for the m. abscessus infection outbreak at GHS. On July 21, 2014, prior to the recall on the Sorin 3T System, SC DHEC released a statement that outlined specific measures that needed to be immediately implemented at GHS as it related to the "cardioplegia machine."[10]

21. On July 15, 2015, the FDA issued a Class II Recall of the Sorin 3T System due to the "potential colonization of organisms, including Mycobacteria, in Sorin Heater Cooler Devices, if proper disinfection and maintenance is not performed per instructions for use."[11]

[8] Id.
[9] Id.
[10] Please see the SC DHEC letter, attached hereto as "Exhibit C." The "cardioplegia machine" is the Sorin 3T System.
[11] Please see the Recall Information from the FDA database, attached hereto as "Exhibit D."

22. The recall instructed all affected customers to follow *new* Instructions for Use, which were outlined in the June 15, 2015 and August 6, 2015 Field Safety Notice Letters[12], issued by i.V. Christian Peis, the Director of Quality Assurance for Sorin.

23. Sorin indicated that it was providing the Field Safety Notice Letter for the following reasons:

A. [To] remind [affected users] of the importance of following the company's disinfection and maintenance procedures;

B. [To] inform [affected users] that there is a possibility that bacteria can become aerosolized when the heater cooler device is operated and serve as a source for contamination; and

C. [To] provide [affected users] with updated instructions for use regarding disinfection and maintenance procedures.[13]

24. Upon information and belief, the Defendants knew or should have known that design and/or manufacturing defects in its Sorin 3T System made it susceptible to bacterial colonization, specifically Mycobacteria, despite any cleaning and disinfection procedures utilized.

25. On December 29, 2015, the FDA issued a Warning Letter to the Defendants, which indicated that its inspection of Sorin's Germany and Colorado facilities revealed that the Sorin 3T System devices had been "adulterated," meaning the "methods used in, or the facilities or controls used for, their manufacture, packing,

[12] Please see the 6/15/15 and 8/6/15 Field Safety Notice Letters, attached hereto as "Exhibit E." These two letters differ in that the Operating Instructions provided in the 6/15/15 letter was intended for distribution to English speaking countries in the European Union (EU), whereas the 8/6/15 letter was intended for distribution in the U.S. Sorin claimed that while "…EU and USA cleaning and disinfection procedures are equivalent, the EU procedures include additional chemicals only available in other countries." Moreover, the U.S. Operating Instructions "…include information specific to the U.S. such as English units of measure and an Indications for Use statement."

[13] Id.

storage, or installation [were] not in conformity with the current good manufacturing practice requirements of the Quality System regulation found at Title 21, Code of Federal Regulations (CFR), Part 820."[14]

26. The FDA noted several other violations by the Defendants in the Warning Letter, which include, but are not limited to, the following:

A. Failure to establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation, as required by 21 CFR 820.30(i);

B. Failure to validate a process, with a high degree of assurance and approved according to established procedures, a process where results cannot be fully verified by subsequent inspection and test, as required by 21 CFR 820.75(a);

C. The devices were misbranded in that Sorin failed or refused to furnish material or information respecting the device that is required by or under § 519 of the Act 21 USC § 360i and 21 CFR Part 803 – Medical Device Reporting;

D. Failure to adequately develop, implement, and maintain written MDR procedures, as required by 21 CFR 803.17;

E. Defendants' Sorin 3T System was misbranded due to its failure to notify the agency of its intent to introduce the device into commercial distribution as required by § 510(k) of the Act, 21 USC §360(k); and

[14] Please see the 12/29/15 Warning Letter, attached hereto as "Exhibit F."

F. Failure to notify the agency of significant labeling changes that affected the safety and effectiveness of the device (i.e., distributing the device with modified instructions for use with respect to the operating, maintaining, cleaning and disinfecting of the device, among other modifications).

27. Contrary to the Defendants' representations and marketing to the FDA, medical community, and to the patients themselves, Defendants' Sorin 3T System has high injury and complication rates, fails to perform as intended, requires patients to undergo additional operations, and has caused severe and sometimes irreversible injuries, conditions, and damages to a significant number of patients, including the Plaintiffs, all of which are violations of Federal and South Carolina State rules and regulations.

28. In violation of Federal and South Carolina State requirements, the Defendants consistently under-reported and withheld information about the propensity of the Sorin 3T System to experience complications and its failure to perform as expected, has misrepresented the efficacy and safety of Defendants' System through various means and media, actively misleading the FDA, the medical community, patients, and the public at large.

29. Defendants knew, and continue to know, that its disclosures to the FDA, the public, and Plaintiffs, were, and are, incomplete and misleading and that the Sorin 3T System was and is causing numerous patients severe injuries and complications, which violates Federal and State requirements. Defendants suppressed this information and failed to accurately and completely disseminate or share this and other critical

information with the FDA, the medical community, health care providers, and patients. As a result, the Defendants actively and intentionally misled the FDA and the public, including the medical community, healthcare providers, and patients, into believing that the Sorin 3T System was safe and effective, leading to the use of Defendants' System during surgical procedures, such as the one undertaken by the Plaintiff, as more fully described herein.

30. In violation of Federal and State rules and regulations, the Defendants failed to perform and/or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Sorin 3T System.

31. As compared to similar systems, feasible and suitable alternative designs, procedures, and instructions for use have existed at all times relevant.

32. The Defendants' 3T Sorin System was at all times relevant, utilized in a manner foreseeable to the Defendants.

33. The Defendants provided incomplete, insufficient, and misleading instructions, training, and information to hospitals and physicians, which is in direct violation of Federal and State regulations and in violation of regulations required pursuant to the 510K Approval of the Sorin 3T System in order to increase the number of hospitals and physicians utilizing the device, thereby increasing its sales.

34. The Sorin 3T System used during Plaintiff's surgical procedure was in the same or substantially similar condition as it was when it left the possession of the Defendants, and in the condition directed by and expected by the Defendants.

35. The injuries, conditions, and complications suffered due to the Sorin 3T System include, but are not limited to, excruciating pain, weakness, excessive additional

and debilitating medical treatment, suffering, and death. Additional information that may be necessary to further establish Plaintiffs' claims will be gathered throughout the discovery process of this litigation since Plaintiffs are privy to limited supporting documentation at this time.

36. Despite Defendants' knowledge of the catastrophic injuries, conditions, and complications caused by the Sorin 3T System, in violation of Federal and State requirements, it continued to manufacture, market, provide inadequate instructions for use, and sell the Sorin 3T System, and also failed to adequately warn, label, instruct, and disseminate information with regard to Defendants' Sorin 3T System both prior to and after the marketing and sale of the System.

FACTS SPECIFIC TO THIS CASE

37. Defendants' Sorin 3T System was used during the Plaintiff's Cardiac Bypass Grafting Procedure, performed at GHS, on or about March 21, 2014, wherein the Plaintiff's surgeon, Dr. Barry Davis, used the device to assist in the cooling and re-warming of Plaintiff's blood. Plaintiff was subsequently discharged from GHS.

38. Upon discharge, Plaintiff's surgical incisions were intact and healing well.

39. Approximately four months later, the Plaintiffs began to notice pain, swelling, tenderness, and a "lump" that had developed in the area of Mr. Thomason's incision site. Mr. Thomason also began to experience fevers and increasing weakness. While undergoing therapy, a therapist noticed the "lump" at Mr. Thomason's incision site and sent him to Dr. Davis for further medical examination.

40. Mr. Thomason was re-admitted to GHS and on or about August 4, 2014, he underwent an Irrigation and Debridement (I&D) procedure with removal of the wires

that had been placed. Moreover, a PICC line was placed and Mr. Thomason was placed on a series of antibiotics.

41. Mr. Thomason was forced to undergo a repeat I&D procedure on August 11th in addition to a muscle flap procedure and wound vac placement.

42. Cultures were obtained and ultimately revealed that Mr. Thomason had contracted the m. abscessus infection. GHS physicians were not sure of the source of his infection at that time.

43. As a result of the m. abscessus infection, Mr. Thomason was forced to undergo numerous additional surgical procedures, medical management, and an extensive course of antibiotic therapy.

COUNT I - NEGLIGENCE

44. The Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation in this Complaint.

45. The Defendants owed a duty of reasonable care to the general public, including the Plaintiffs, when it designed, labeled, manufactured, assembled, inspected, tested, marketed, placed/distributed into the stream of commerce, instructed, and sold the Sorin 3T System, to assure that the product was in compliance with FDA regulations and not defective and/or unreasonably dangerous for its intended purposes and foreseeable uses.

46. The Defendants breached this duty by designing, labeling, manufacturing, assembling, inspecting, testing, marketing, distributing, instructing, and selling/distributing the Sorin 3T System in a defective and unreasonably unsafe condition including, but not limited to, its propensity for the colonization of organisms,

including mycobacteria.

47. The Defendants owed Plaintiffs a duty of reasonable care to discover defects and/or errors in the machine and to inform and/or warn the FDA and Plaintiffs of a defect once it was discovered. The Defendants violated these duties when it failed to do so, which further placed the Plaintiffs at risk for harm and injury.

48. The Sorin 3T System differed in design, manufacture, packaging, storing, warning, labeling, instructions for use, distribution and advertising from the System that received approval through the 510K process, and thus the design, manufacture, packaging, storing, warning, labeling, instructions for use, distribution and advertising of the Sorin 3T System used at GHS during the Plaintiff's heart procedure was done so in violation of those requirements.

49. The Defendants had the duty to comply with and not deviate from statutory requirements, which amongst other things, require that the device be manufactured, labeled, and designed according to the standards laid out in the FDA approval. The Defendants violated these duties when it failed to comply therewith and distributed a device that deviated from the statutory requirements.

50. As a direct and proximate result of Defendants' violations, the Plaintiffs have suffered severe debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost enjoyment of life, lost income, and pain and suffering, all of which are continuous in nature.

51. Under South Carolina law, the Defendants' violations of said Federal statutes and regulations establish a prima facie case of common law negligence.

52. Under South Carolina common law, a money damages remedy exists for

violation of the Act and regulations promulgated pursuant to the Act, which resulted in an unreasonably dangerous product proximately causing injuries to the Plaintiffs.

COUNT II- STRICT PRODUCTS LIABILITY

53. The Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation in this Complaint.

54. As a direct and proximate result of Defendants' violations of Federal and State laws, Plaintiffs have suffered severe debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost enjoyment of life, lost income, and pain and suffering, all of which are continuous in nature.

55. Under South Carolina law, the Defendants' violations of said regulations establish a prima facie case of strict liability in tort.

56. Under South Carolina common law, a money damages remedy exists for violation of the Act and regulations promulgated pursuant to the Act, which resulted in an unreasonably dangerous product proximately causing injuries to the Plaintiffs.

COUNT III - BREACH OF EXPRESS WARRANTY

57. The Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation in this Complaint.

58. The Defendants warranted, both expressly and impliedly, through its marketing, advertising, distributors and sales representatives, that the Sorin 3T System was of merchantable quality, and fit for the ordinary purposes and uses for which it was sold.

59. The Defendants are aware that health care providers and patients, including the Plaintiffs, rely upon the representations made by the Defendants when

choosing, selecting, and purchasing its products, including the Sorin 3T System.

60. Due to the defective and unreasonably dangerous design, labeling, manufacturing, and distribution of the Sorin 3T System, which was in violation of statutory requirements and regulations, the product was neither of merchantable quality, nor fit for the ordinary purposes for which it was sold, presenting an unreasonable risk of injury to patients, including the Plaintiffs, during foreseeable use.

61. The Defendants' violations of Federal and State statutory rules and regulations and the defective and unreasonably dangerous condition of the Sorin 3T System constituted a breach of the Defendants' express and implied warranties, and such breaches were a direct and proximate cause of the incident and injuries described herein, and for which Plaintiffs are entitled to attorney's fees, compensatory, and punitive damages in an amount to be proven at trial.

COUNT IV - BREACH OF IMPLIED WARRANTIES

62. The Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation in this Complaint.

63. Defendants warranted, both expressly and impliedly, through its marketing, advertising, distributors and sales representatives, that the Sorin 3T System was of merchantable quality, and fit for the ordinary purposes and uses for which it was sold.

64. When the Sorin 3T System was used during the Plaintiff's heart procedure, the system was being used for the original purposes for which it was approved and intended.

65. Plaintiffs, individually and/or by and through the healthcare provider, relied upon Defendants' implied warranties of merchantability in consenting to have the heart procedure performed with assistance of the Sorin 3T System.

66. Defendants breached these implied warranties of merchantability because the Sorin 3T System was neither merchantable nor suited for the intended uses as warranted.

67. Defendants' breach of its implied warranties resulted in the use of an unreasonably dangerous and defective product during Plaintiff's heart procedure, placing Plaintiff's health and safety in jeopardy.

68. As a direct and proximate result of the Defendants' breach of the aforementioned implied warranties and violations of Federal and State laws, the Plaintiffs have suffered significant mental and physical pain and suffering, sustained permanent injury, underwent, and continue to undergo, rigorous and debilitating medical treatment, suffered a loss of enjoyment of life, suffered financial and/or economic loss, including, but not limited to, obligations for past, present, and future medical services and expenses, and/or lost income and other damages, for which Plaintiffs are entitled to attorney's fees and compensatory and punitive damages in an amount to be proven at trial.

COUNT V - NEGLIGENT MISREPRESENTATION

69. The Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation in this Complaint.

70. The Defendants negligently misrepresented to the FDA, the medical community, Plaintiffs, and the public, the defective nature and extent of adverse

reactions and labeling errors of the Sorin 3T System.

71. The Defendants failed to adhere to FDA regulations by failing to appropriately report all of the information and knowledge in their possession in regards to the dangers that the Defendants knew their product presented, including, but not limited to, the fact that colonization of mycobacteria inside the Sorin 3T System could occur if specific disinfection and maintenance procedures were not implemented.

72. Had the Defendants accurately and truthfully represented to the FDA, the medical community, the Plaintiffs, and the public, the material facts relating to the risks of the Sorin 3T System, the Plaintiffs and/or Plaintiff's healthcare provider would not have utilized the Sorin 3T System as it did during the Plaintiff's heart procedure.

73. Under South Carolina law, the Defendants' violations of said Federal statutes and regulations establish a prima facie case of negligent misrepresentation.

74. Under South Carolina common law, a money damages remedy exists for violation of the Act and regulations promulgated pursuant to the Act, which resulted in the negligent misrepresentation of an unreasonably dangerous product proximately causing injuries to the Plaintiffs.

75. As a direct and proximate result of the Defendants' negligent misrepresentations and violations as outlined above, the Plaintiffs have suffered significant mental and physical pain and suffering, sustained permanent injury, underwent, and continue to undergo, rigorous and debilitating medical treatment, suffered a loss of enjoyment of life, suffered financial and/or economic loss, including, but not limited to, obligations for past, present, and future medical services and expenses, and/or lost income and other damages, for which Plaintiffs are entitled to

attorney's fees and compensatory and punitive damages in an amount to be proven at trial.

COUNT VI - MISREPRESENTATION BY OMISSION

76. The Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation in this Complaint.

77. Throughout the relevant time period, Defendants knew that the Sorin 3T System was defective and unreasonably unsafe for intended purposes, which the Defendants failed to properly report to the FDA.

78. The Defendants were under a duty to disclose to the FDA, the Plaintiffs, and the medical community, the defective nature and extent of adverse reactions and labeling errors of the system because the Defendants were in a superior position to know the true quality, safety, and efficacy of the Sorin 3T System.

79. The Defendants concealed from and/or failed to disclose to the FDA, Plaintiffs, Plaintiff's healthcare providers, and the medical community that it's Sorin 3T System was defective, unsafe, and unfit for the purposes intended, and that it was not of merchantable quality.

80. The facts concealed and/or not disclosed to the FDA, Plaintiffs, or the medical community, were material facts that a reasonable person would have considered important in deciding whether to utilize the Sorin 3T System, and were facts that were required pursuant to Federal and State statutes and regulations.

81. Under South Carolina law, the Defendants' violations of said Federal statutes and regulations establish a prima facie case of misrepresentation by omission.

82. Under South Carolina common law, a money damages remedy exists for

violation of the Act and regulations promulgated pursuant thereto, which resulted in Defendants' misrepresentation by omission of an unreasonably dangerous product that proximately caused injuries to the Plaintiffs.

83. As a direct and proximate result of the Defendants' concealment and misrepresentations by omission and violations outlined above, the Plaintiffs have suffered significant mental and physical pain and suffering, sustained permanent injury, underwent, and continue to undergo, rigorous and debilitating medical treatment, suffered a loss of enjoyment of life, suffered financial and/or economic loss, including, but not limited to, obligations for past, present, and future medical services and expenses, and/or lost income and other damages, for which Plaintiffs are entitled to attorney's fees and compensatory and punitive damages in an amount to be proven at trial.

COUNT VII – VIOLATION OF THE S.C. UNFAIR TRADE PRACTICES ACT, S.C. CODE ANN. §39-5-20

84. The Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation in this Complaint.

85. At all times relevant to this action, the South Carolina Unfair Trade Practices Act codified at S.C. Code Ann. §39-5-20 was in effect. The section states:

a. Unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful.

b. It is the intent of the legislature that in construing paragraph (a) of this section the courts will be guided by the interpretations

given by the Federal Trade Commission and the Federal Courts to § 5(a) (1) of the Federal Trade Commission Act (15 U.S.C. 45(a)(1)), as from time to time amended.

86. The Defendants have engaged in deceptive acts or practices in violation of the South Carolina Unfair Trade Practices Act, including but not limited to, utilizing deception, fraud, misrepresentation, concealment, omission, and suppression of research from investigations, adverse events reported to the FDA, and clinical trials regarding the safety, efficacy, instructions for use, and the unreasonably dangerous nature of the Sorin 3T System.

87. The Defendants violated the South Carolina Unfair Trade Practices Act by concealing, omitting, and failing to inform the FDA, the Plaintiffs, the medical community, and other purchasers of the failures, adverse reactions, complications, and the insufficiency of the Instructions For Use as it related to the Sorin 3T System.

88. Defendants' deceptive acts and practices occurred during a course of conduct involving trade or commerce.

89. As a direct and proximate cause of the Defendants' violations of Federal requirements and the South Carolina Unfair Trade Practices Act, the Plaintiffs have sustained, severe physical and emotional injuries and economic loss, which are continuous in nature, for which Plaintiffs are entitled to attorney's fees and compensatory and punitive damages in an amount to be proven at trial.

COUNT VIII - LOSS OF CONSORTIUM

90. The Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation in this Complaint.

91. Due to the Defendants' deviations as further outlined herein, this Loss of Consortium claim allows a remedy to Mrs. Thomason, the wife of Mr. Thomason, against the Defendants.

92. As a direct and proximate result of the Defendants' deviations from the applicable standards of care as expressed herein, Mrs. Thomason has been, and will continue to be, deprived of the consortium, society, comfort, protection, and services of her husband, thereby causing and continuing to cause economic damages, grief, sorrow, mental anguish, emotional distress, and pain and suffering and prays for judgment against the Defendants as set forth in this Complaint.

PUNITIVE DAMAGES

93. The Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation in this Complaint.

94. The acts, omissions, and violations of the Defendants as set forth herein constitute intentional, fraudulent, malicious and/or reckless conduct. Accordingly, Plaintiffs are entitled to an award of punitive damages.

ACTUAL DAMAGES

95. The Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation in this Complaint.

96. As a direct and proximate result of the acts, omissions, and violations of the Defendants alleged herein, the Plaintiffs suffered injuries and damages. The injuries and damages for which Plaintiffs seek compensation from the Defendants include, but are not limited to:

a. physical pain and suffering of a past, present and future nature;

b. emotional pain and suffering of a past, present and future nature;

c. permanent impairment and scarring;

d. medical bills and expenses of a past, present and future nature;

e. loss of earnings;

f. loss of earning capacity;

g. loss of enjoyment of life;

h. pre- and post-judgment interest;

i. statutory and discretionary costs;

j. loss of consortium of spouses; and

k. any and all such further relief, both general and specific, to which they may be entitled to under the premises.

PRAYERS FOR RELIEF

97. The Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation in this Complaint.

98. **WHEREFORE, PREMISES CONSIDERED,** the Plaintiffs bring this Complaint against the Defendants for personal injuries and pray for a judgment against the Defendants for compensatory damages, in an amount considered fair and reasonable by a jury and for all such further relief, both general and specific, to which Plaintiffs may be entitled under the premises.

99. **WHEREFORE, PREMISES CONSIDERED,** the Plaintiffs bring this Complaint against the Defendants for personal injuries and pray for a judgment against the Defendants for punitive damages in an amount considered fair and reasonable by a

jury and for all such further relief, both general and specific, to which they may be entitled under the premises.

Respectfully submitted,

PARHAM SMITH & ARCHENHOLD, LLC

s/ S. Blakely Smith
s/ Ashlee Edwards Winkler
S. Blakely Smith (Fed ID No.: 6954)
Ashlee Edwards Winkler (Fed ID No.: 12090)
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Attorneys for Plaintiffs

JURY REQUEST

The Plaintiffs hereby respectfully request a trial by jury.

s/ S. Blakely Smith
s/ Ashlee Edwards Winkler
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